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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 08/28/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/894,356

Applicant(s)

RITCHART ET AL.

Examiner

Jonathan ML Foreman

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 - 36, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 - 36, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 20 – 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 30 recite, “flexible [band/severing element] being wrapped about a distal end of said tissue sampling apparatus”. Since the “tissue sampling apparatus” is only set forth in the preamble, the exact location of the band/severing element is unclear. It is unclear whether the band/severing element is wrapped about the distal end of the cutter or of the body.

Although unclear, the claims have been reviewed by the examiner as best understood at this time in order to continue with the examination.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 20 – 22, 29, 30, 35, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,133,360 to Spears.

In reference to claim 20, Spears discloses a tissue sampling apparatus comprising: a body having a primary lumen (18) for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a cutter (22; Col. 3, lines 21 - 24) having a distal cutting edge and being movable both distally and proximally relative to said body (Col. 3, line 24); and a flexible band (20; Col. 6, lines 12 - 14) having an opening disposed therein and being wrapped about a distal end of said tissue sampling apparatus and movable for severing a distal end of said tissue sample received in the primary lumen (Col. 3, lines 43 - 51).

In reference to claim 21, Spears discloses the body comprising an outer sheath (58), and the cutter being disposed within the outer sheath.

In reference to claim 22, the cutter as disclosed by Spears is considered by the examiner to be selectively rotatable in that it can be rotated by the user while being placed into or removed from the device.

In reference to claim 29, Spears discloses the body lumen sized to accommodate a plurality of tissue samples (Col. 9, lines 30 - 33).

In reference to claim 30, Spears discloses a body having a primary lumen (18) for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a flexible severing element (20) being wrapped about a distal end of said tissue sampling apparatus (Col. 2, line 60, said flexible severing element being movable relative to said primary lumen in order to sever a distal end of said tissue sample (Col. 3, lines 43 - 51).

In reference to claim 35, Spears discloses a cutter (22; Col. 3, lines 21 - 24) having a distal cutting edge and being movable both distally and proximally relative to the body (Col. 3, line 24).

In reference to claims 39 and 40, Spears discloses cutting along a length of a tissue mass to provide a partially severed tissue sample core (Col. 3, lines 24 - 27); positioning the partially severed

Art Unit: 3736

core in the lumen; and conveying a flexible cutter around a distal end of the tissue receiving lumen to sever the distal end of the tissue sample core (Col. 3, lines 43 – 49). Spears discloses storing multiple severed tissue samples within the lumen (Col. 9, lines 30 – 33).

5. Claims 20 – 23 and 30 – 33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,015,391 to Rishton et al.

In reference to claim 20, Rishton et al. discloses a tissue sampling apparatus comprising: a body having a primary lumen (18) for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a cutter (Col. 3, lines 25 - 30) having a distal cutting edge and being movable both distally and proximally relative to said body (Col. 3, lines 18 - 22); and a flexible band (16) having an opening disposed therein and being wrapped about a distal end of said tissue sampling apparatus and movable for severing a distal end of said tissue sample received in the primary lumen (Col. 3, lines 57 – 62).

In reference to claim 21, Rishton et al. discloses the body comprising an outer sheath (12), and the cutter being disposed within the outer sheath.

In reference to claim 22, the cutter as disclosed by Rishton et al. is considered by the examiner to be selectively rotatable in that it can be rotated by the user while being placed into or removed from the device.

In reference to claim 23, Rishton et al. discloses an actuator (Col. 2, lines 52 – 54) disposed proximally of the body.

In reference to claim 30, Rishton et al. discloses a body having a primary lumen (14) for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a flexible severing element (16) being wrapped about a

Art Unit: 3736

distal end of said tissue sampling apparatus, said severing element being movable relative to said primary lumen order to sever a distal end of said tissue sample (Col. 3, lines 57 – 62).

In reference to claim 31, Rishton et al. discloses an actuator (24) disposed proximally of the body (Col. 2, lines 50 – 54).

In reference to claim 32, Rishton et al. discloses the actuator being adapted to move the severing element in order to move the opening relative to the body (Col. 3, lines 57 – 62).

In reference to claim 33, the lever discloses by Rishton et al. is considered by the examiner to meet the limitation of a trigger.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,133,360 to Spears in view of U.S. Patent No. 4,667,684 to Leigh.

In reference to claims 24, 26 and 27, Spears discloses selectively rotating and retracting and extending the cutter. However Spears fails to disclose a trigger for actuating the cutter. Leigh discloses a biopsy device having a trigger to actuate the cutter (Col. 3, lines 49 – 53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Spears to include a trigger as taught by Leigh to actuate the cutter in order to better mechanize the biopsy procedure so the procedure can be performed rapidly and expeditiously to minimize discomfort to the patient (Col. 3, lines 53 – 60). In addition it would have

Art Unit: 3736

been obvious to one having ordinary skill in the art at the time the invention was made to replace the trigger with a cam nut in that the trigger and the cam nut perform the same function and would therefore be interchangeable.

8. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,015,391 to Rishton et al.

In reference to claim 34, Rishton et al. discloses the actuator comprising a trigger. However Rishton et al. fails to disclose the actuator comprising a cam nut. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the trigger with a cam nut in that the trigger and the cam nut perform the same function and would therefore be interchangeable.

9. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,133,360 to Spears in view of U.S. Patent No. 5,913,857 to Ritchart et al.

In reference to claim 36, Spears fails to disclose a probe fitting being configured to receive a sensing probe having an aperture which communicates with the primary lumen. However, Ritchart et al. discloses a tissue sampling apparatus having a probe fitting being configured to receive a sensing probe having an aperture which communicates with the primary lumen (Col. 10, lines 35 – 44). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus as disclosed by Spears to include a probe fitting being configured to receive a sensing probe having an aperture which communicates with the primary lumen as taught by Ritchart et al. to aid in the removal of a tissue sample from a patient's body.

Art Unit: 3736

Allowable Subject Matter

10. Claims 25 and 28 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant submitted no arguments with respect to the claims. However, had Applicant submitted arguments with respect to the claims they would be moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
August 25, 2003



**MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**